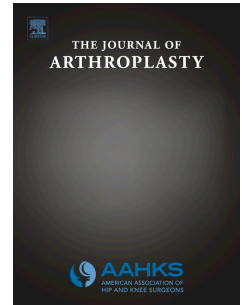


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**COMPARISON OF FUNCTIONAL OUTCOMES BETWEEN THE FIRST AND
SECOND KNEE IN STAGED BILATERAL TOTAL KNEE ARTHROPLASTY
WITH DIVERSE INTERVALS BETWEEN STAGES**

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COMPARISON OF FUNCTIONAL OUTCOMES BETWEEN THE FIRST AND SECOND KNEE IN STAGED BILATERAL TOTAL KNEE ARTHROPLASTY WITH DIVERSE INTERVALS BETWEEN STAGES

ABSTRACT

Background: To analyze if the length of interval time between stages influenced functional and quality of life outcomes in patients with staged bilateral primary TKA.

Methods: Retrospective comparative study between 93 patients with an interval between stages of 6-8 months (6-month group), 112 of 12-14 months (1-year group), and 108 of 24-26 months (2-year group). Outcome variables were Knee Society scores (KSS), Western Ontario and McMaster Universities (WOMAC), Short-Form (SF12) and patient satisfaction.

Results: Overall, the mean follow-up for the first TKA was 8.2 (range, 7-10) years, and for the second TKA 6.7 (range, 5-10) years. At last follow-up, functional and patient-related outcomes were similar for both knees, regardless of the interval. However, mental score and patient satisfaction were significantly better for the second than for the first TKA in the 2-year group. Age did not correlate significantly with the functional scores but was significantly correlated with the mental score.

Conclusion: The performing staged bilateral TKA with a wide interval between surgeries provided equivalent functional outcomes and quality of life for both knees. Postoperative outcomes were not affected by the length of the time interval between procedures or age. Our results can help the surgeon to inform to the patients reliably about they can expect in the delay of a second knee replaced. Thus patients could make an informed decision.

Key words: Total knee arthroplasty; Staged bilateral; Functional outcome; Quality of life; Age

INTRODUCTION

Total knee arthroplasty (TKA) is an effective treatment to relieve pain and restore physical functioning in patients with end-stage knee osteoarthritis [1]. Many patients with knee osteoarthritis have bilateral symptoms [2], with a prevalence of severe bilateral involvement as high as 19% [3]. In such patients, the surgeries can be performed either simultaneously or in a staged operation with a variable length of time between each arthroplasty. However, choosing between both bilateral procedures is controversial [4]. The decision to proceed with bilateral surgery is made by the patient following discussion with the surgeon, on the basis of the expectations, patient's physical condition and relative contraindications. Thus, many elderly patients with bilateral osteoarthritis can decide to have TKA on the contralateral side after the remission phase of the first stage [5]. Sesen et al [6] reported a refusal rate for the second TKA of 37 %, and the patients older than 70 years had a higher refusal rate compared to younger patients. On the other hand, many other patients present severe stage in one knee but mild to moderate in the contralateral knee, which does not require surgery until after a long time [7].

Many studies have been published on bilateral TKA, but most of them focused on complications and socioeconomic implications of simultaneous versus staged TKA [8]. Some others have compared overall functional outcomes between patient cohorts underwent these bilateral procedures, although most of them involved relatively small cohorts of patients or short follow-up [9,10]. However, studies comparing the functional outcomes of the first and second knee in patients underwent staged bilateral procedures are few [9,11,12]. In addition, the majority of patients included in those studies had an interval between stages less than 12 months, and follow-up was up to 1 year in all but one study [11]. Thus, although objective outcomes for each knee may be reliable, quality of life outcomes for each knee may be difficult to assess if the interval between surgeries was short. To our knowledge, no studies

had compared the functional and patient-reported outcomes between both knees in patients underwent staged bilateral TKA with a relatively long time interval between stages and a medium-term follow-up.

The aim of this study was to analyze if the length of interval time between stages influenced functional and quality of life outcomes in patients with staged bilateral primary TKA.

PATIENTS AND METHODS

This was a retrospective cohort study of patients prospectively assessed. The study was approved by our Institutional Review Board and informed consent was required for a new evaluation. Patients who underwent bilateral TKA at our centre between 2006 and 2012 were identified in our departmental arthroplasty database. This database prospectively collected clinical and radiological data in a standardized manner with annual postoperative follow-up for at least 5 years. TKA was recommended to patients who had radiologically Kellgren and Lawrence grade III or IV knee osteoarthritis with related symptoms. In the case of bilateral knee involvement, the first procedure was selected based on symptoms and patient preference, and the time interval between stages was decided based on surgeon's recommendations and patient preference. Simultaneous bilateral TKA was not performed at our centre.

Inclusion criteria were staged bilateral primary TKA, aged over 60 years, and minimum postoperative follow-up of 5 years for each knee. Exclusion criteria were posttraumatic or inflammatory arthritis, neurological disorder or need for constrained TKA in any knee. Like other [12], because the objective was to compare functional and patient-related outcomes between both knees, patients who had revision TKA were also excluded to limit outcome bias.

There were 351 patients with staged bilateral TKA. Of these, 18 had surgical revision of one knee and 20 other patients had one knee with follow-up less than 5 years. All these 38 patients

were excluded. The 313 remaining patients were classified into 3 groups according to the interval time between stages. There were 93 patients with an interval between 6 and 8 months (6-month group), 112 between 12 and 14 months (1-year group), and 108 between 24 and 26 months (2-year group). Baseline characteristics of each group are shown in Table 1.

Surgical protocol

Surgeries were performed by several consultant surgeons, although the same surgeon operated both knees for the same patient. In addition, all procedures were standardized at our centre and the same surgical techniques and postoperative protocols were used for both knees of all patients. All surgeries were performed in operating room with laminar flow, under spinal anaesthesia. A standard anterior midline skin incision and medial parapatellar arthrotomy were used in all patients. Standard operative techniques with intramedullar alignments for femur and tibia were used for all patients. The same modular TKA systems were used in all patients (Trekking, Samo, Italy). Fixation was hybrid (cementless femur and cemented tibia). Depending on the ligament balance at the time of surgery, a cruciate-retaining (CR) or posterior-stabilized (PS) model was used. All patellae were routinely resurfaced with an all-polyethylene cemented design.

According to the standard protocol, all patients received antibiotic prophylaxis with first generation cephalosporin for 24 hours (started 1 hour prior to skin incision) and thromboembolic prophylaxis with low-molecular-weight heparin for 30 days. Standardized at our centre, continuous passive knee motion started on the first postoperative day and from the third day active motion under the supervision of the therapist and full weight-bearing were allowed.

Evaluations

All patients had been prospectively assessed, clinical and radiologically, preoperatively and postoperatively at each annual visit. Functional assessment was assessed by the Knee Society scores (KSS) [13], and patient-reported outcomes with the Western Ontario and McMaster Universities (WOMAC) [14] and Short-Form (SF12) [15] questionnaires validated for our country. The WOMAC score was transformed to a 0-100 scale, so a higher value implies a better outcome, and the result was shown overall for pain and function. Patient satisfaction for each knee was measured at the time of the latest follow-up with a 0-10 visual analogue scale (VAS). Comorbidity was assessed by the American Society of Anesthesiologists (ASA) scores [16].

Radiological evaluation was performed using standing anteroposterior, lateral and standard skyline views. The latest radiographs were assessed for presence and location of radiolucent lines on the basis of Knee Society zones [17].

Statistical analysis

A posteriori analysis of statistical power was performed with a non-inferiority test. Considering our sample size, a minimal clinically important difference [18] of 10 with standard deviation of 10 for the physical component summary of SF12, and alpha error of 0.05 %, the study had a power of 84%, which was considered appropriate.

Statistical analyses were performed with SPSS software v. 15.0 (SPSS Inc., Chicago, USA). Normal distribution was determined by the Kolmogorov-Smirnov test. For paired comparison between pre- and post-operative and between first and second knees data, the McNemar test was used in categorical variables, and the paired t-test or non-parametric Wilcoxon signed-rank test in continuous variables. Variance analysis (Anova) was use for comparison between groups. Correlations were made by the Pearson coefficient test. Statistical significance was considered for p values less than 0.05.

RESULTS

Overall, the mean follow-up for the first staged TKA was 8.2 (range, 7-10) years, and for the second TKA 6.7 (range, 5-10) years. All the knees of each group improved significantly from preoperative to the last follow-up.

In 6-month and 1-year groups (Table 2), there were no significant differences in objective or patient-related scores between the first and second knee (all, $p < 0.05$). In 2-year group, there were no significant differences in KSS scores, ROM, WOMAC or SF12-physical scores (all, $p < 0.05$), but SF12-mental score was significantly higher in the second knee compared to the first knee ($p = 0.041$).

Comparing the three groups (Table 2), there were no significant differences between the first knees or the second knees in any score, except in patient satisfaction. Regarding patient satisfaction at the last follow-up for each knee (Table 2), there was no significant difference between the first and second knee in the 6-month group ($p = 0.411$) and 1-year group ($p = 0.055$). However, patient satisfaction was significantly higher in the second knee compared to the first knee ($p = 0.012$). Comparing the three groups, there was no significant difference in patient satisfaction for the first knee ($p = 0.454$). However, although for the second knee there were no significant differences between 1-month and 1-year groups ($p = 0.181$) or between 1-year and 2-year groups ($p = 0.140$), patient satisfaction was significantly higher for the second knee in the 2-year group compared with the 6-month group ($p = 0.030$). Comparing TKA types, CR or PS, there were no significant differences in satisfaction ($p = 0.732$).

Regarding the second staged TKA, the interval time between stages did not influence the KSS-knee ($r = 0.4$, $p = 0.425$) or KSS-function ($r = 0.5$, $p = 0.237$) score at the last follow-up.

At the last follow-up, there were no significant differences between the TKA types (CR versus PS) in KSS-knee ($p = 0.612$), KSS-function ($p = 0.497$), ROM ($p = 0.116$), WOMAC

($p=0.197$) or SF12 ($p=0.392$). Likewise, the age at the time of the first TKA did not correlate significantly with the KSS-function ($r=0.7$, $p=0.317$), WOMAC-function ($r=-0.3$, $p=0.637$) or SF12-physical ($r=-0.4$, $p=0.086$) scores at the last follow-up in either the first or second staged TKA. However, the age at the time of the second TKA was significantly correlated with SF12-mental score at the last follow-up in the 2-year group ($r=-0.6$, $p=0.040$).

DISCUSSION

The main finding of the present study was that functional and quality of life scores were not significantly different between the first and second knee in any time interval. However, mental score and patient satisfaction were significantly better for the second than for the first TKA in the 2-year group but not in shorter intervals. Likewise, patient satisfaction for the second knee was significantly higher in the 2-year group compared to 6-month group. Age at the time of the first TKA did not correlate significantly with the functional scores for the second knee, but was significantly correlated with the mental score.

Like us, Gabr et al [19] found similar KSS, WOMAC and SF12-physical scores between knees at the last follow-up, and better SF12-mental score for the second knee compared to the first. Other studies reported no significant differences between both knees at the last follow-up [9,11]. Like us, Scott et al [20] found higher satisfaction for the second TKA.

Many patients have bilateral symptomatic knee osteoarthritis [21]. For these patients, simultaneously or staged bilateral TKA has been proposed. However, the reported results have been conflicting, such as similar [23,24], better [10], or worse [25] outcomes with simultaneous TKA compared to staged bilateral TKA. Moreover, it has been reported that patients undergoing bilateral simultaneous TKA tend to be younger and have better health status [3,26]. The decision to proceed with simultaneous or staged bilateral surgery must be done by the patient after receiving information from the surgeon, and it based on the physical

condition and expectations of the patient. Sesen et al [6] reported that 37% of patients refused the second TKA, especially patients older than 70 years. On the other hand, many other patients with unilateral TKA present only mild to moderate symptoms in the contralateral knee that does not require surgery in that time [7]. Subsequent arthroplasty of the contralateral knee following unilateral TKA has been reported in 36% of patients [27,28] with a wide interval between surgeries [29]. Thiam et al [30] reported that not all patients with bilateral knee osteoarthritis accepted bilateral TKA because unilateral TKA could restore quality of life. These authors found also that 28% of patients with bilateral knee osteoarthritis did not return for the second TKA within 2 years. Moreover, the patient's experience with the first TKA has shown to have influence on the decision for contralateral surgery [5].

Some authors [5,19] have reported higher patient expectation for the second than for the first TKA. Gabr et al [20] found improved function and psychological well-being after the second surgery. Becker et al [31] reported that patient satisfaction was correlated with the functional outcomes, and the indication for TKA should consider the general health and emotional role in order to predict patient's outcome.

Time interval between surgeries did not influence the results in our study. A recent national database study [26] reported a ratio of simultaneous to staged bilateral TKA of 1:4, and 94% of staged bilateral TKA, and other recent study [32] found no significant differences in functional outcomes or complication rate between surgery interval from 3 months to 1 year. Moreover, many patients decide to have TKA on the contralateral side after the remission phase of the first stage [5]. A study [33] of patients with unilateral TKA reported that the nonoperated limb tended to weaken after 2 years of surgery, possibly representing changes resulting from aging and progression of osteoarthrosis in some patients with unilateral TKA.

In the present study, age did not influence outcomes. Abram et al [9] also reported that age did not affect the postoperative score in either the first or second staged TKA.

Strengths of the present study included the analysis of a single-centre with standardized surgical and postoperative management. The size of our samples provided adequate statistical power to detect significant differences. To our knowledge, this was the first study comparing diverse intervals between TKA. In addition, this study had the longest follow-up published to date comparing both knees. However, this study has also several limitations. Firstly, the study was retrospective. Nevertheless, the data had been collected prospectively in a systematic and standardized way, so the number of variables of interest was not limited. The cohort consisted in selected patients due to the exclusion of those who need revision TKA. This was done in an effort to minimize variables within the study population and thereby enhance the isolation of knee outcome parameters. We believe that this fact enhanced the obtained comparative results. In a study such as this, the patients compared themselves in the first and second knee. Therefore, the patients could have difficulty discerning which of the two knees had a greater or lesser effect on their quality of life.

CONCLUSION

This study suggested that performing staged bilateral TKA with a wide interval between surgeries provided equivalent functional outcomes and quality of life for both knees. Postoperative functional outcomes and quality of life were not affected by the length of the time interval between procedures or age. Our results can help the surgeon to inform to the patients reliably about they can expect in the delay of a second knee replaced. Thus patients could make an informed decision.

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313 **Table 1.** Preoperative data at the time of each surgery

	6-month group n= 93	1-year group n= 112	2-year group n= 108	p-value
Gender, F/M	69/24	79/33	77/31	0.833
ASA, I-II/III-IV	71/22	81/31	74/34	0.467
BMI, kg/m ²				
1 st knee	31.2 (5.9)	30.9 (6.3)	30.6 (6.7)	0.798
2 nd knee	30.4 (6.1)	31.4 (6.4)	31.7 (5.8)	0.296
p-value	0.364	0.556	0.197	
ROM, degrees				
1 st knee	88.4 (11.3)	89.2 (10.8)	89.8 (10.6)	0.661
2 nd knee	89.9 (12.1)	90.4 (12.6)	91.2 (11.3)	0.739
p-value	0.383	0.445	0.348	
KSS-knee score				
1 st knee	39.4 (13.7)	40.4 (13.3)	41.8 (14.4)	0.463
2 nd knee	41.2 (14.3)	42.3 (15.1)	44.3 (13.8)	0.299
p-value	0.379	0.318	0.194	
KSS-function score				
1 st knee	40.8 (12.7)	41.7 (12.8)	42.9 (13.8)	0.522
2 nd knee	43.5 (13.2)	42.8 (13.6)	45.5 (12.7)	0.294
p-value	0.156	0.533	0.151	
WOMAC				
1 st knee	40.3 (10.1)	41.2 (9.9)	41.7 (9.6)	0.599
2 nd knee	42.4 (11.2)	42.9 (11.7)	43.8 (12.4)	0.692
p-value	0.181	0.241	0.165	
SF12-physical				
1 st knee	29.7 (8.3)	31.1 (8.4)	30.4 (7.8)	0.473
2 nd knee	31.3 (10.1)	33.3 (10.3)	34.6 (9.4)	0.064
p-value	0.239	0.081	0.001	
SF12-mental				
1 st knee	36.4 (12.6)	36.9 (10.7)	38.4 (9.4)	0.390
2 nd knee	38.7 (10.3)	39.3 (10.1)	41.3 (9.6)	0.148
p-value	0.174	0.085	0.025	

314 Continuous data as mean (SD).

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316

317

Table 2. Outcomes for both TKA

	6-month group	1-year group	2-year group	p-value
KSS-knee				
1 st knee	86.1 (7.1)	87.0 (7.9)	85.9 (7.1)	0.504
2 nd knee	86.7 (8.2)	85.9 (9.1)	86.2 (6.4)	0.773
p-value	0.594	0.335	0.744	
KSS-function				
1 st knee	86.3 (8.2)	86.9 (8.4)	85.6 (9.7)	0.773
2 nd knee	87.0 (9.1)	88.1 (9.8)	87.3 (7.9)	0.656
p-value	0.582	0.326	0.159	
ROM				
1 st knee	102.6 (9.8)	104.7 (11.1)	101.8 (10.6)	0.112
2 nd knee	105.5 (10.3)	102.9 (10.0)	104.1 (11.7)	0.224
p-value	0.051	0.203	0.131	
WOMAC				
1 st knee	82.5 (11.2)	86.2 (12.4)	83.4 (13.5)	0.081
2 nd knee	84.3 (12.3)	87.1 (10.9)	85.1 (12.9)	0.123
p-value	0.298	0.564	0.345	
SF12-physical				
1 st knee	43.9 (9.4)	44.2 (9.1)	43.8 (8.7)	0.943
2 nd knee	44.6 (8.8)	45.7 (9.4)	44.3 (8.6)	0.477
p-value	0.601	0.226	0.671	
SF12-mental				
1 st knee	44.3 (10.2)	44.8 (10.3)	45.1 (9.5)	0.850
2 nd knee	45.6 (10.6)	46.4 (9.8)	47.6 (8.4)	0.329
p-value	0.395	0.234	0.041	
Satisfaction				
1 st knee	7.3 (1.5)	7.0 (1.7)	7.1 (1.9)	0.454
2 nd knee	7.1 (1.8)	7.4 (1.4)	7.7 (1.6)	0.030
p-value	0.411	0.055	0.012	

Data as mean (SD)